UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,700	09/25/2003	Masahiro Kajiwara	6854-24-1	6367

22852 7590 05/14/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
05/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
	20070416-a

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

New Examiner's Answer with "(11) Related Proceedings Appendix" [blank] being the change.

D. Margaret Seaman
Primary Examiner
Art Unit: 1625

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/669,700
Filing Date: September 25, 2003
Appellant(s): KAJIWARA, MASAHIRO

Mark J. Feldstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20 September 2006 appealing from the Office action mailed 6 February 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai in view of Richardson (Drugs, Sept 1998, Vol 56(3), pp 307-335). Hirai teaches the treatment of ulcers. When urease acid increases, the gastric mucosa is injured (thinned) and the stomach wall is left open for injury (ulcer). Hirai teaches the use of the same compounds as instantly claimed on the same patient population in the same manner in the same injury area with the same/expected outcome. However, Hirai does not teach the combination of an additional pharmacological active ingredient. Richardson teaches the treatment of ulcers, again the same patient population with the same injury area with the same expected outcome, using omeprazole or other active ingredients in combination with one or more antibacterials (see page 307 last 4 lines). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use the combination of a compound to treat ulcers with one or more antibacterials with the reasonable expectation of successful treatment of ulcers because it is conventional (See Richardson page 307 last line) to administer ulcer treatment compounds with antibacterial compounds for a combination ulcer treatment and both Hirai teaches conventional ulcer treatment compounds. "It is prima facie obvious to combine two

compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).]

Rationale: Richardson teaches the combination of known ulcer treatment compounds with known antibacterial compounds to eradicate H. pylori in over 90% of cases (page 307 last line).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Hirai, JP 04077476

Richardson, Paul, Drugs, Vol 56(3), pp 307-335, September 1998.

http://www.cdc.gov/ncidod/dbmd/diseaseinfo/hpylori_g.htm

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following ground(s) of rejection are applicable to the appealed claims:

(Non-Final rejection from office action of 8/19/2005)

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 9-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hirai (JP 04077476). The rejection is maintained for reasons of record.

The 1,2-benzoisothiazol-3-(2H)-one (English abstract; also page 15, Table 1, Example 2) in the pharmaceutical composition for treating ulcer (English abstract), wherein gastric mucosa has been injured, would inherently inhibit the urease and act as an anti-Helicobactor pylori agent as recited in the instant claims, since it is well known in the art that Helicobactor pylori is the culprit of peptic ulcer disease.

Applicant maintains that Hirai does not specifically teach the inhibition of urease activity or inhibition of a Helicobacter pylori activity. However, the method of treating ulcer in a patient using the same prior art compound would inherently inhibit urease activity and Helicobacter pylori activity, or any mechanisms of actions. In the instant, this is especially true when Helicobacter pylori is commonly known to be the cause of ulcer or the recurrence of ulcer, as it is specifically described on page 28, lines 3-6 of the specification.

Applicant contends that not all ulcer is caused by Helicobacter pylori, and common ulcer treatments are not directed to inhibition of urease or Helicobacter pylori activity as shown for Prilosec (omerprazole) (PDR reference submitted with the response).

The mechanism of action, however, fails to set a demarcation from the prior art method of using the same compound for treating the same disease. Moreover, omerparzole, an H+/K+-ATPase inhibitor, has been shown also to inhibit urease and affect Helicobacter pylori viability in vitro (Kuhler et al. J. Med. Chem. 1995, 38(25): 4906-4916).

Applicants argues that since Hirai fails to teach the treatment of ulcers by inhibiting urease or H. Pylori activity, then the rejection falls. For inherency to stand, the same patient population must be treated. The first page of the specification states

> Urea secreted from the gastric parietal is hydrolyzed by urease to produce ammonia and carbon dioxide. Ammonia has a strong mucosa injurious effect, thereby to cause a blood flow disorder of the gastric mucosa, and also neutralizes gastric acid, thereby to enable habitation of Helicobacter pylori within the stomach under a severe acidic environment. In case Helicobacter pylori adheres to the gastric mucosa, epithelial cells of the gastric mucosa produce Interleukin-8 (IL-8) as a kind of cytokines, while IL-8 acts on neutrophils, thereby to cause migration and activation of neutrophils. The activated neutrophils form phagocytosis and phagosome and also cause production of active oxygen and degranulation. The produced active oxygen itself causes a mucosa injury and induced to hypochlorous acid through an action of chlorine and myeloperoxidase in the stomach, and is also converted into monochloramine by means of ammonia, thus causing a cell injury.

The bacteria (H.Pylori) starts a chain reaction which creates high acidity in the stomach. This high level of acidity damages the mucosa. The ulcer is caused by this damaged mucosa. The compounds used in the instant method claims therefore treat the high levels of acid in the stomach and allow the ulcer to heal. To treat the bacterial infection, (see page 15 of the instant specification) coadministeration of the compounds of formula (1) with other active ingredients such as antibiotics must be done. The antibiotics treat the bacterial infection and the compounds of formula (1) treat the high levels of acid. Due to this, the same patient population is being treated by the same compound as

taught by the prior art. Therefore, the instant method claims are inherently taught by the prior art.

(Final Rejection of office action dated 2/06/2006)

3. Claims 9-16 and now claims 17-20 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Hirai (JP 04077476). The rejection is maintained for reasons of record.

Applicants argues that since Hirai fails to teach the treatment of ulcers by inhibiting urease or H. Pylori activity, then the rejection falls. For inherency to stand, the same patient population must be treated. The patient population being treated is people with ulcers. This is the same population. Ulcers are the gastric mucosal injury outcome caused by urease. If the gastric mucosa is injured, then the stomach wall is exposed, and an ulcer is made. The same compound is being used to treat the same patient population for the same end treatment (ulcer). The method of treating ulcer in a patient using the same prior art compound would inherently inhibit urease activity and helicobacter pylori activity or any mechanism of action. The mechanism of action fails to set a demarcation from the prior art method of using the same compound for treating the same disease in the same patient population. Due to this, the rejection is upheld.

(10) Response to Argument

Claim Group 1: Claims 9, 10, 12, 13, 15, 16, 18 and 20

First, Applicant argues that Hirai at most discloses the treatment of ulcers and does not inherently disclose the claimed methods of treating gastric mucosa injury caused by urease or H.Pylori.

It is the Examiner's position that Hirai teaches the treatment of ulcers which is the same patient population that is instantly being claimed because only a patient population having gastric mucosa injury would have an ulcer. The high levels of acid in the stomach damage the mucosa lining the stomach. This damage allows the high levels of acid to put a hole in the stomach wall (ulcer). Hirai teaches that the compounds of Hirai (which is the same compounds as instantly claimed) will suppress the secretion of gastric acid. The lower acid levels will allow the gastric mucosa to recover and the ulcer will heal. Due to this, the same patient population is treated with the same compound with the same result: healing the ulcer.

Second, Applicant argues that Perricone v. Medicis Pharmaceutical Corp. decision supports the conclusion because "is not...whether if applied to [a damaged area] would inherently treat that damage, but whether [the prior art] discloses the application of its composition [to the specified type of damaged area]."

It is the Examiner's position that Hirai [the prior art] teaches the application of the same compound/composition to the same damaged area, namely the ulcer/stomach (page 2 line 4 of the translation of Hirai) and the treatment of

gastrointestinal diseases, for example gastric ulcer, duodenal ulcer or Zollinger-ellison syndrome (page 38 last 3 lines of the page of Hirai). Due to this, the same compound is applied to the same damaged area, which fits the test of Perricone v. Medicis Pharmaceutical Corp.

Third, Applicant argues that to establish inherency, the evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference..." and that "[I]nherency...may not be established by probabilities or possibilities".

It is the Examiner's position that inherency has been established without anything missing. The same patient population with the same condition is being treated in the same matter with the same compounds, namely the compounds taught by Hirai. The patient population is people with ulcers. The same condition being treated is gastrointestinal diseases (gastric ulcers, duodenal ulcers...ulcers). The same manner is being used to treat the same conditions, namely oral use of the same benzisothiazolone derivatives.

Fourth, Applicant argues that in Perricone, inherency is established by the treatment of the same condition, in the same treatment area by the same treatment compound and this is not currently being upheld by the instant situation by Hirai.

It is the Examiner's position that the same condition (ulcers (page 2 of translation) or gastrointestinal diseases (page 38 of translation)) is being treated. The same treatment area is being treated, namely stomach or intestinal areas. The same

compound is being used, namely the benzisothiazolone derivatives as described by Hirai and instantly claimed.

Fifth, Applicant argues that not all ulcers are caused by urease or H. Pylori.

It is the Examiner's position that this is true. However, greater than 50% of all people worldwide have H. pylori infections in their stomach. Further, 9 out of 10 ulcers are caused by H. pylori. The same treatment as instantly claimed, namely treatment of a condition by the use of an isothiazole compound alone of the instant formula (1) for claims 9-13 and 16-20 is fully encompassed by the teachings of Hirai. Only claims 14-15 require an additional element.

Sixth, Applicant argues that Hirai is directed to treating ulcers by reducing acid.

It is the Examiner's position that this is true. This also is true of the instant claims 9-13 and 16-20 because only the same compounds are being claimed to treat the same patient population with the same conditions and in the same manner as taught by Hirai. Only claims 14-15 require anything different from the Hirai prior art. If the same compounds are being used in the same manner to the same affected area, then inherently, the same method of treatment is being used as taught by Hirai.

Seventh, Applicant argues that Hirai simply does not teach (or even suggest) the method as claimed.

It is the Examiner's position that the same patient population is being treated of the same condition with the same compounds in the same manner. This is inherency.

Claim Group 2: Claims 11, 17 and 19

Eighth, Applicant argues that claims 11, 17 and 19 pertain to the treatment of chronic gastritis and Hirai does not teach or suggest a method of treating chronic gastritis.

It is the Examiner's position that gastritis is defined as inflammation of the stomach due to action of a corrosive agent. The corrosive agent could be stomach acid which Hirai teaches the production of such will be suppressed by use of the benzothiazole compounds. Further, the claims 11, 17 and 19 use only the same compound as taught by Hirai, in the same patient population in the same manner as instantly claimed with the same outcome. This is inherency.

Claim Group 3: Claim 14

Ninth, Applicant argues that the rejection of record (Hirai) does not anticipate or make obvious the rejection of claim 14 due to the combination of the active ingredient of claim 1 with additional pharmacological active ingredients.

It is the Examiner's position that this combination is lacking in Hirai. The new grounds of rejection (Hirai in view of Richardson, above section 6) renders obvious the combination of the ulcer treating compound (Hirai) with other active ingredients (Richardson, page 307) with the expectation of treating over 90% of cases.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

D. Margaret Seaman
Primary Examiner
Art Unit 1625

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

John L LeGuyader
Director
Technology Center 1600

Conferees:

Jean Witz
Quality Assurance Specialist
Technology Center 1600

Thomas McKenzie
SPE, Art Unit 1625

Evidence Appendix